MAR 1 3 2013

SECTION 5 – 510(k) Summary
Modified Capiox® FX15 and FX25 Oxygenator/Reservoir

Submitter Information:

This submission was prepared in February 2013 by:

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This submission was prepared for:

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Manufacturer/Sterilizer
150 Maimaigi-cho
Fujinomiya City, Shizuoka Pref.
Japan 418-0015
Registration #9681834

Device Names/Classifications:

Proprietary Name	Classification Name	Common Name
Capiox® FX15 and FX25 Hollow Fiber Oxygenator/Reservoir	Cardiopulmonary Bypass Oxygenator (Code: DTZ)	Oxygenator
	Cardiopulmonary Bypass Blood Reservoir (Code: DTN)	Blood Reservoir

Predicate Device:

The device submitted in this 510(k) maintains characteristics that are substantially equivalent in intended use, design, technology/principles of operation, materials and specifications to the following devices:

- Terumo's Capiox® FX15 and FX25 Oxygenator/Reservoir – K071494.

Intended Use:
The Capiox FX Hollow Fiber Oxygenator and Arterial Filter is intended to be used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery.

The integrated arterial filter is intended to filtrate non-biologic particles and emboli and to facilitate air bubble removal from the blood flowing through the cardiopulmonary bypass circuit.

The integrated heat exchanger is used to warm or cool blood and/or perfusion fluid as it flows through the device.

The hardshell reservoir is used to store blood during extra-corporeal circulation from the venous line and the cardiotomy line. The reservoir contains a venous section that is comprised of a filter and defoamer to facilitate air bubble removal. The cardiotomy section of the reservoir contains a filter to remove particulate matter and a defoamer to facilitate air bubble removal. The 3-liter and 4-liter reservoirs may be used for Vacuum Assisted Drainage procedures and Post Operative Chest Drainage Procedures.

The Capiox FX15 is for use with patients when the required blood flow rate will not exceed 5.0 L/min. when used with a 4 Liter Reservoir; and when the required blood flow rate will not exceed 4.0 L/min. when used with a 3 Liter Reservoir.

The Capiox FX25 is for use with patients when the required blood flow rate will not exceed 7.0 L/min.

The Capiox FX Oxygenator/Reservoir/Arterial Filter assemblies can be used in procedures lasting up to 6 hours.

Principles of Operation and Technology:
The modified Capiox® FX15 and FX25 Oxygenator utilizes porous fiber technology to facilitate the transfer of gases between a blood-phase environment and a gas-phase environment for the intent of satisfying the gas exchange needs of a patient during cardiopulmonary bypass surgery. A fiber bundle offers the porous membrane surface to sufficiently permit the movement of gases through the walls of the hollow fibers via diffusion.

The modified Capiox® FX15 and FX25 device has an integrated heat exchanger that is comprised of stainless steel encased in a polycarbonate housing. The stainless steel acts as a heat transfer material that permits heat that is generated from a temperature controlled external water bath to transverse across the walls of the stainless steel to effect the necessary temperature change upon circulating blood.

With respect to the filtration of arterial blood, the modified Capiox® FX15 and FX25 Oxygenator/Reservoir relies upon mechanical entrapment of particulates and emboli within the filter mesh as a means to remove those particulates from the blood.

Design and Materials:
With respect to the design of the oxygenator, the design of the modified Capiox® FX15 and FX25 oxygenator device is unaffected by the changes being incorporated at this time. The subject of this Special 510(k) is a modification being made to the detachable Hardshell Reservoir.

With respect to the design of the Arterial Filter, the filter contained within the oxygenator module is unaffected by the changes being incorporated at this time. The subject of this Special 510(k) is a modification being made to the detachable Hardshell Reservoir.

With respect to the design of the Hardshell Reservoir, the reservoir component remains identical to the design of the original reservoir that was cleared by FDA with K071494 – except that a positive pressure relief valve will be included on the lid of the reservoir. The intent of the relief valve is to eliminate excessive pressure that *could* accumulate in a reservoir during bypass procedures.

The materials that are used in the construction of the Capiox® FX15 and FX25 Oxygenator/Reservoir, but are not limited to, nylon, polycarbonate, stainless steel, polyvinyl chloride, polyurethane, polyester, polypropylene, polyethylene terephthalate, polyethylene and X-Coating™.

Performance Evaluations:
Clinical studies involving patients are not necessary to demonstrate substantial equivalence of the subject device to the predicate devices. Substantial equivalence is demonstrated with the following *in-vitro* performance evaluations:

- Pressure Relief Valve-to-Reservoir Interface Testing
- Relief Valve performance following application of vacuum to the reservoir
- Assessment of reservoir pressure during simulated bypass procedure at flow rates of 1,2,3,4 and 5 liters per minute
- Sterilization Assessment
- Drop Testing
- Vibration Testing

Substantial Equivalence Comparison:
The information presented in this section depicts a comparison between the subject of this 510(k) submission, the modified Capiox® FX15 and FX25 Oxygenator/Reservoir, and the predicate (unmodified) Capiox® FX15 and FX25 Oxygenator/Reservoir.

- ***Comparison of Intended Use:***
  The modified Capiox® FX15 and FX25 devices and the predicate Capiox® FX15 and FX25 devices are exact in their intended uses:

  The Capiox® FX Hollow Fiber Oxygenator and Arterial Filter is intended to be used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery.

The integrated arterial filter is intended to filtrate non-biologic particles and emboli and to facilitate air bubble removal from the blood flowing through the cardiopulmonary bypass circuit.

The integrated heat exchanger is used to warm or cool blood and/or perfusion fluid as it flows through the device.

The hardshell reservoir is used to store blood during extra-corporeal circulation from the venous line and the cardiotomy line. The reservoir contains a venous section that is comprised of a filter and defoamer to facilitate air bubble removal. The cardiotomy section of the reservoir contains a filter to remove particulate matter and a defoamer to facilitate air bubble removal. The 3-liter and 4-liter reservoirs may be used for Vacuum Assisted Drainage procedures and Post Operative Chest Drainage Procedures.

The Capiox® FX15 is for use with patients when the required blood flow rate will not exceed 5.0 L/min. when used with a 4 Liter Reservoir; and when the required blood flow rate will not exceed 4.0 L/min. when used with a 3 Liter Reservoir.

The Capiox® FX25 is for use with patients when the required blood flow rate will not exceed 7.0 L/min.

The Capiox® FX Oxygenator/Reservoir/Arterial Filter assemblies can be used in procedures lasting up to 6 hours.

- ***Duration of Use:***
  The modified Capiox® FX15 and FX25 device and the predicate device can both be used in procedures lasting up to 6 hours.

- ***Comparison of Labeling:***
  Both the modified Capiox® FX15 and FX25 devices and the predicate Capiox® FX15 and FX25 devices are offered with adequate Instructions for Use and other product labeling as required by regulation. The Instructions for Use for the modified Capiox® FX15 and FX25 device are presented in the Appendices of this submission; the Instructions for Use for the predicate Capiox® devices are also presented in the Appendices of this submission.

- ***Comparison of Principles of Operation & Technology:***
  Both the modified Capiox® FX15 and FX25 Hollow Fiber Oxygenator and the predicate Capiox® FX15 and FX25 devices utilize the exact same technologies and principles of operation. The technology of the Capiox® FX15 and FX25 have not changed as a result of the product modification that is the subject of this application.

  The predicate Capiox® FX15 and FX25 and the predicate device are exactly the same with respect to operation and technology.

- ***Comparison of Design:***
  With respect to the design of the modified Capiox® FX15 and FX25 device, there have been no design changes except that the modified device will be available with a pressure relief valve attached to the lid assembly of the hardshell reservoir.

  The design of the oxygenator module and other components of the assembled device remain unaffected by the modification to include a pressure relief valve.

- ***Comparison of Materials:***
  With respect to materials of construction, the subject reservoir and the predicate reservoirs are constructed of the exact same materials. The positive pressure relief valve that is included with the modified reservoir is constructed of polycarbonate and nylon.

- ***Comparison of Performance:***
  The modified Capiox® FX15 and FX25 device exhibits equivalent performance to the unmodified predicate device – as there have been no changes made to the finished device that would alter the performance of the device.

Conclusion:
In summary, Terumo deems the modified Capiox® FX15 and FX25 device is substantially equivalent to the predicate unmodified Capiox® FX15 and FX25 device with respect to intended use, duration of use, design, materials, principles of operation, performance and specifications. It is further noted that any recognized differences do not raise any new issues of patient/user safety or product effectiveness.

Substantial Equivalence Statement:
The modified Capiox® FX15 and FX25 devices and the predicate Capiox® FX15 and FX25 devices are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the subject device and the predicate devices do not raise new issues of safety and effectiveness.

Additional Safety Information:
- Sterilization conditions have been validated to provide a Sterility Assurance Level (SAL) of 10^{-6}. Terumo further asserts that the ethylene oxide residues will not exceed the maximum residue limits at the time of product distribution.

- Terumo maintains biocompatibility studies as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

Conclusion:
In summary, the modified Capiox® FX15 and FX25 devices are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the predicate devices (unmodified Capiox® FX15 and FX25) identified in this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2013

Terumo Cardiovascular Systems Corporation
c/o Eileen Dorsey
125 Blue Ball Road
Elkton, MD 21921

Re: K130520
Trade/Device Name: CAPIOX FX15 and FX25 Hollow Fiber Oxygenator/Reservoir with Integrated Arterial Filter (with X-Coating)
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: February 27, 2013
Received: February 28, 2013

Dear Ms. Dorsey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – Indications for Use

Modified Capiox® FX15 and FX25 Oxygenator/Reservoir

510(k) Number (if known): Unknown at time of Submission

Device Name: **CAPIOX® FX15 and FX25 Hollow Fiber Oxygenator with Integrated Arterial Filter and Hardshell Reservoir**

Indications For Use:

The Capiox FX Hollow Fiber Oxygenator and Arterial Filter is intended to be used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery.

The integrated arterial filter is intended to filtrate non-biologic particles and emboli and to facilitate air bubble removal from the blood flowing through the cardiopulmonary bypass circuit.

The integrated heat exchanger is used to warm or cool blood and/or perfusion fluid as it flows through the device.

The hardshell reservoir is used to store blood during extra-corporeal circulation from the venous line and the cardiotomy line. The reservoir contains a venous section that is comprised of a filter and defoamer to facilitate air bubble removal. The cardiotomy section of the reservoir contains a filter to remove particulate matter and a defoamer to facilitate air bubble removal. The 3-liter and 4-liter reservoirs may be used for Vacuum Assisted Drainage procedures and Post Operative Chest Drainage Procedures.

The Capiox FX15 is for use with patients when the required blood flow rate will not exceed 5.0 L/min. when used with a 4 Liter Reservoir; and when the required blood flow rate will not exceed 4.0 L/min. when used with a 3 Liter Reservoir.

The Capiox FX25 is for use with patients when the required blood flow rate will not exceed 7.0 L/min.

The Capiox FX Oxygenator/Reservoir/Arterial Filter assemblies can be used in procedures lasting up to 6 hours.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner